



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0283]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Final Guidance for Industry on Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes to be Documented in Annual Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Final Guidance for Industry on Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes to be Documented in Annual Reports " has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850,

PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On November 6, 2013; the Agency submitted a proposed collection of information entitled "Final Guidance for Industry on Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes to be Documented in Annual Reports" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0758. The approval expires on January

31, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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